REMARKS/ARGUMENTS

Claims 1-2, 4-5, 7-8 are pending in this application and presented for examination. Claims 1 and 4 have been amended. Claims 3 and 6 have been canceled without prejudice or declaimer. Reconsideration is respectfully respected.

I. FORMALITIES

Claims 1 and 4 have amended. The features of claims 3 and 5, which have been canceled, have been incorporated into claims 1 and 4. Further, support for the amendments to claims 1 and 4 is found, for example, on page 5, last paragraph, bridging to page 6, and Table 3 on page 15 wherein PEG4000, PEG6000 and PEG 20000, and Pluronic P85 or Pluronic F68 are recited. Further, with respect to Pluronic P85 or Pluronic F68, the average number of repeating oxyethylene units of one ethylene oxide chain length is 27, and 80, respectively. This is recited at the top of page 6. Thus no new matter has been entered with the foregoing amendments to the claims. As such, Applicants respectfully request that they be entered.

Under M.P.E.P § 821.04, if Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. Process claims, which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance.

In an earnest effort to advance prosecution, Applicants have amended process claim 1 to be commensurate in scope to product claim 4. In view of the remarks and evidence set forth below, Applicants believe the application is in condition for allowance. As such, Applicants respectfully request that the Examiner rejoin the method claims (claims 1 and 2) to this application.

II. REJECTION UNDER 35 USC §103(a)

Claims 4-8 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over WO 98/51306 (U.S. Patent No. 6,184,230). Claims 1 and 4 has been amended to recite that the drug has anti-*H. pylori* activity. Further, claims 1 and 4 have been amended to set forth that the polyethylene glycol is selected from the group consisting of PEG4000, PEG6000 and PEG 20000, and the a polyoxyethylene polypropylene copolymer is either Pluronic P85 or Pluronic F68. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

III. OBJECTIVE EVIDENCE REBUTS ANY *PRIMA FACIE* CASE OF OBVIOUSNESS

Applicants maintain that a *prima facie* case of obviousness has not been established. However, Applicants can rebut a *prima facie* case of obviousness by presenting comparative test data showing that the claimed invention possesses unexpectedly improved properties or properties that the prior art does not possess. *In re Dillion*, 16 U.S.P.Q. 1897, 1901 (Fed. Cir. 1990).

Applicants submit that the comparative data filed with the application rebuts any *prima facie* case of obviousness. The Examiner's attention is respectfully directed to Experiments 2 and 3, starting on page 12 and bridging to pages 13, 14 and Table 3 on page 15. Experiment 2 states:

> In order to study adsorption of a drug from an aqueous phase onto an oil phase (model of mucous layers), an *in vitro* test system wherein mixing of the oil components in the aqueous phase is prevented was constructed by immobilizing the oil phase with a gelling agent and separating it from the aqueous phase of a drug suspended in a mucin solution.

Table 3 shows that without the addition of excipient, only 19% of the active agent is absorbed. However, with the addition of PEG4000, PEG6000 and PEG20000 as an excipient in the formulation, the absorption increases to 42%, 72% and 79%, respectively. These results

are surprising and unexpected. Further, Table 3 also shows that the addition of Pluronic P85 or Pluronic F68 as excipients in the formulations increase the absorption rate to 40% and 68%, respectively. This too is surprising and unexpected.

As recited on page 17, at the bottom paragraph:

> It is clear from the results in Experiments 1 through 4 that the main factor in the compound A *in vivo* anti-*H. pylori* activity-augmenting mechanism of Macrogol 6000 is that the Macrogol 6000 forms an aggregate with the mucin in the mucus components so that the drug is taken up when this aggregate is adsorbed on the oil that is a mucus component, with the amount of drug adsorbed *in vitro* on the immobilized oil phase increasing when Macrogol 6000 is added. The *in vivo* anti-*H. pylori* activity of compound A increased when Macrogol 6000 was added; therefore, it was shown that there is a correlation with an increase in the amount of drug adsorbed on the mucus component (oil) *in vitro*. Furthermore, there was also a correlation between adsorption of a drug on an oil and the average number of repeating oxyethylene units of one ethylene oxide chain length, with 17 or greater being the average number of repeating oxyethylene units of one ethylene oxide chain length with which there is a significant increase in adsorption of a drug on an immobilized oil phase.

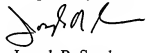
As each of the excipients now claimed exceeds this average number of repeating oxyethylene units of one ethylene oxide chain length, the formulations as presently claimed produce unexpectedly improved absorption properties. These unexpected advantageous properties represent objective evidence sufficient to rebut a *prima facie* case of obviousness. Accordingly, the Examiner is respectfully requested to withdraw the 35 U.S.C. §103(a) rejection.

IV. CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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